

**Notice of Allowability**

Application No.

10/622,893

Applicant(s)

YUAN ET AL.

Examiner

Art Unit

Malgorzata A. Walicka

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/22/06.
2. ☒ The allowed claim(s) is/are 1,14,23-25 and 32-61.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

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Amendment after Final Action, comprising amendments to the claims and Remarks filed June 22, 2006 is acknowledged. Claims 2-13, 16-20, and 62-86 have been previously canceled; claims 15, 21 and 22 have been currently cancelled. Claims 1 and 23 have been amended. Claims 1, 14, 23-25 and 32-61 are under examination. Claims 26-31 have been withdrawn as directed to the non-elected invention.

### **Detailed Action**

#### **1. Rejections**

##### **1.1. 35 USC § 112, second paragraph**

Rejection of claims 1 and 23-24 made in the Final Action of Feb. 23, 2006 (final action) is withdrawn, because the claim 1 has been amended.

Rejection of claims 15 made in the final action is moot because the claim has been cancelled.

##### **1.2. 35 USC § 103**

**A.** Claims 1, 14 and 32 were finally rejected ~~rejected~~ under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (Primary structures of fungal fructosyl amino acid oxidases and their application to the measurement of glycated proteins, Eur. Biochem. 1996, 242, 499-5050, Takahashi et al. A (Molecular Cloning and Expression of Amadoriase Isoenzyme (Fructosyl Amine-oxygen Oxidoreductase EC 1.5.3) from *Aspergillus fumigatus*, J. Biol. Chemistry 1997, 6, 12505-12307) in view of common knowledge in the field of protein expression as exemplified by US Patent 6,194,200

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(Expression Systems for Preparation of Polypeptides in Procaryotic cells, issued Feb. 27, 2001).

This rejection is now withdrawn, because claim 1 has been amended.

**B.** Claims 33-37, 39-41, 45, 53, 54, 57, 58 and their dependent claims 38, 40, 42, 46-52, 55-56, as well as claims 59-61 were finally rejected as being unpatentable over European Patent EP0 821064 A2, published Jan. 28, 1998 (the EU Patent), included in the IDS, and further in view of Takahashi et al. A and US Patent 6,194,200. The rejection is now withdrawn because claim 1 has been amended.

## **2. Examiner's amendment**

Please cancel claims 26-31 directed to the nonelected invention.

Authorization for this examiner's amendment was given in a telephone interview with Jie Zhou on July 18, 2006.

## **3. Allowance**

Claims 1, 14 23-25 and 32-61 are allowed. The following is the examiner reason for allowance.

Applicants disclose a chimeric protein, which is useful in testing levels of protein glycation in patients. Although the chimeric protein contains an enzyme that has been already known; see the prior art used in rejection under 35 USC 103, the protein contains additionally a leader sequence of SEQ ID NO:1 at its N-terminus and a leader

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of SEQ ID NO:4, constructed by Applicants, at the C-terminus. Although a known protein having a leader attached to its terminus is obvious; see the obviousness rejection in previous actions, the chimeric protein containing a leader at N- and C-termini is not obvious. Because Applicants possess also an antibody specific for SEQ ID NO: 4 the claimed chimeric protein can be detected or isolated using said antibody. In conclusion, the claims are ALLOWED

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.


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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
1652